510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
ADVIA® 2120 with Autoslide

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _K042225_

1. Intended Use

The *Bayer ADVIA 2120 with Autoslide* is a quantitative, automated hematology analyzer that provides a leukocyte differential count and reticulocyte analysis for in vitro diagnostic use in clinical laboratories. In addition, the system provides the added capability to automatically prepare and stain high-quality blood smears on a microscope slide.

2. Predicate Device

Proprietary Name: Bayer ADVIA 120 Hematology Analyzer
Common name: Automated Hematology Analyzer
Classification name: Automated hematology complete blood cell counter (§ 864.5200), differential cell counter (§ 864.5220)
Classification number: 21 CFR Parts 864.5200, 864.5220, Class II
510(k) Number: K971998

3. Device Information

Proprietary Name: Bayer ADVIA 2120 Hematology Analyzer with Autoslide System
Common name: Automated Hematology Analyzer and Automated Maker and Stainer
Classification name: Automated hematology complete blood cell counter (§ 864.5200), differential cell counter (§ 864.5220) and automated slide stainer (§ 864.3800)
Classification number: 21 CFR Parts 864.5200, 864.5220, 864.3800 , Class II

4. Device Description

The ADVIA 2120 Hematology system with Autoslide is an integrated option of a Hematology analyzer with complete blood cell count, leukocyte differential cell count, reticulocyte analysis capability and a slide stainer designed to provide reflexive slide making/staining without user intervention based upon pre-selected, user-definable criteria.

The ADVIA 2120 Hematology system with Autoslide consists of the following: an analytical module that aspirates, dilutes, and analyzes whole blood samples; an autosampler that automatically mixes, identifies, and presents the samples for processing; a computer workstation that controls the instrument, provides primary user interface with the instrument and manages the data produced by the instrument; a printer that optionally generates reports based on the instrument results and an autoslide module that prepares a wedge smear from a drop of blood,

places it on a microscope slide and stains the slide in accordance with Wright, Wright-Giemsa and May-Grunwald Giemsa Staining techniques.

The ADVIA 2120 with Autoslide reports the following hematological parameters:

<u>White Blood Cell Parameters</u>
WBC- white blood cell count
Neut- neutrophil count (percentage and absolute counts)
Lymph- lymphocyte count (percentage and absolute counts)
Mono- monocyte count (percentage and absolute counts)
Eos- eosinophil count (percentage and absolute counts)
Baso- basophil count (percentage and absolute counts)
LUC- large unstained cell count (percentage and absolute counts)

<u>Red Blood Cell Parameters</u>
RBC- red blood cell count
Hct- hematocrit
MCV- mean corpuscular volume
RDW- red cell volume distribution width
CHCM- hemoglobin concentration mean
HDW- hemoglobin concentration distribution width

<u>Hemoglobin Parameters</u>
Hgb- hemoglobin concentration
MCH- mean corpuscular hemoglobin
MCHC- mean corpuscular hemoglobin concentration

<u>Platelet Parameters</u>
Plt- platelet count
MPV- mean platelet volume

<u>Reticulocyte Count</u>
Retic- reticulocyte count (percentage and absolute counts)
MCVg- mean corpuscular volume of all gated red cells
MCVr- mean corpuscular volume of reticulocytes
CHCMg- hemoglobin concentration mean of all gated red cells
CHCMr- hemoglobin concentration mean of reticulocytes
CHg- mean hemoglobin content of all gated red cells
CHr- mean hemoglobin content of reticulocytes

In addition the ADVIA 2120 with Autoslide reports the following parameters with Cerebrospinal Fluid samples using the CSF method cleared for use on the ADVIA 120 under K022331:

White Blood Cell Parameters
WBC- white blood cell count
Neut- neutrophil count (percentage and absolute counts)
Lymph- lymphocyte count (percentage and absolute counts)
Mono- monocyte count (percentage and absolute counts)
Eos*- eosinophil count (percentage and absolute counts)
MN- mononuclear count (percentage and absolute counts)
PMN- polymorphonuclear count (percentage and absolute counts)

Red Blood Cell Parameters
RBC- red blood cell count

* For Laboratory Use Only (not reportable)

The ADVIA 2120 with Autoslide supports the following staining techniques:

Wright Stain
Wright-Giemsa Stain
May-Grunwald Stain

5. **Summary of Technological Characteristics**

The principles of operation of the ADVIA 2120 Hematology System with Autoslide are similar to those of the ADVIA 120, the only difference is the ability of the ADVIA 2120 Hematology System with Autoslide to prepare a wedge smear from a drop of blood, place it on a microscope slide and stain the slide in accordance with Wright, Wright-Giemsa and May-Grunwald Giemsa Staining techniques.

The Autoslide module will dispense a drop of blood from the sample on a slide, the smearing assembly will create a smear using the surface tension of the blood. After smearing, the slide is sent to the printer where information on patient demographics can be printed along with any other necessary information. If staining is required, the slide moves into the stainer, where the slide is stained according to the staining method in use. Once staining is complete, the slide is transferred to a rack and processing is complete.

The hematological parameters supported by the ADVIA 2120 with Autoslide are the same and use the same technology as the predicate device, the ADVIA 120, below is a summary of the technological characteristics for each parameter:

The White Blood Cell parameters are derived through a combination of laser light scatter, as well as light scatter and absorption from a tungsten light source based on cellular peroxidase activity.
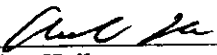
The Red Blood Cell and Platelet parameters are derived through laser light scatter and refractive index.

The Hemoglobin parameters are based on a modification of the manual cyanmethemoglobin methods developed by the International Committee for Standardization in Hematology.

The Reticulocyte parameters are derived through a combination of laser light scatter and absorption of a nucleic acid dye.

6. Conclusion

Based on all the information provided as part of this submission the ADVIA 2120 Hematology system with Autoslide is substantially equivalent to the ADVIA 120 Hematology System.

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Andres Holle
Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

_____8/17/04_____
Date

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer HealthCare LLC
Diagnostics Division
511 Benedict Avenue
Tarrytown, New York 10591

SEP 1 7 2004

Re: k042251
        Trade/Device Name: ADVIA® 2120 with Autoslide
        Regulation Number: 21 CFR § 864.5220
        Regulation Name: Automated differential cell counter
        Regulatory Class: II
        Product Code: GKZ, KPA
        Dated: August 18, 2004
        Received: August 20, 2004

Dear Mr. Holle:

We have reviewed your Section 510(k) premarket notification of intent to market the device
referenced above and have determined the device is substantially equivalent (for the indications
for use stated in the enclosure) to legally marketed predicate devices marketed in interstate
commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to
devices that have been reclassified in accordance with the provisions of the Federal Food, Drug,
and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).
You may, therefore, market the device, subject to the general controls provisions of the Act. The
general controls provisions of the Act include requirements for annual registration, listing of
devices, good manufacturing practice, labeling, and prohibitions against misbranding and
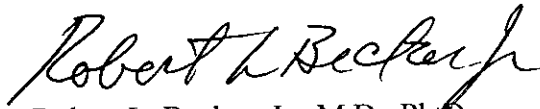adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it
may be subject to such additional controls. Existing major regulations affecting your device can
be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA
may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean
that FDA has made a determination that your device complies with other requirements of the Act
or any Federal statutes and regulations administered by other Federal agencies. You must
comply with all the Act's requirements, including, but not limited to: registration and listing (21
CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice
requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter
will allow you to begin marketing your device as described in your Section 510(k) premarket
notification. The FDA finding of substantial equivalence of your device to a legally marketed
predicate device results in a classification for your device and thus, permits your device to
proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042251

Device Name: ADVIA® 2120 with Autoslide

Indications For Use:

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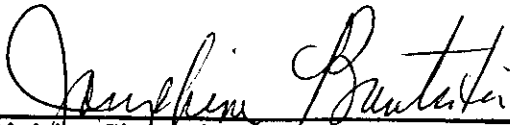
Prescription Use ___X___   AND/OR   Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)   (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)____K042251_____

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